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Informed Consent

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This article will expand on the brief informed consent information presented in the last newsletter by summarizing Wisconsin Administrative Code HFS 94, Patient Rights and Resolution of Patient Grievance requirements. This article briefly addresses the patient grievance procedures required of various health care providers.

HFS 94 is promulgated under the authority of s. 51.61 (5) b and (9) Wisconsin Statutes., to implement s. 51.61, Stats, concerning the rights of patients receiving treatment for mental illness, a developmental disability, alcohol abuse or dependency or other drug abuse or dependency. Individuals who receive health care services have basic rights, including the right to informed consent and complaint, regardless of where they receive services. This also applies to nursing homes, adult family homes, and community based residential facilities and others, that serve patients or residents with a mental illness, a developmental disability, alcohol abuse or dependency or other drug abuse or dependency.

Under s. HFS 94.02 (22), "Informed consent" or "consent" means written consent voluntarily signed by a patient who is competent and who understands the terms of the consent, or by the patient's legal guardian or the parent of a minor, as permitted under s. 51.61 (6) and (8), Stats., without any form of coercion, or temporary oral consent obtained by telephone. Informed consent is an important process through which Wisconsin healthcare patients or residents are assured rights, and informational needs are explained, before important health decisions are made. Except in emergency care situations, informed consent to treatment must be obtained for every change in treatment, including prescription medications.

The primary manner in which informed consent is executed is through a document signed by the patient, the patient's legal guardian, or by the parent of a minor patient, and is kept as part of the patient's clinical record. For an informed consent document to be complete, it must declare that the patient, or the person acting on the patient's behalf, has been provided with specific, complete and accurate information, and allow the time to consider the proposed treatment, including seeking additional advice, for the patient's mental illness, developmental disability, alcoholism or drug dependency.

HFS 94.03(1) spells out the seven elements facilities must address when patients, legal guardians, or parent(s) of minor patients execute informed consent documents. They include:(1) benefits of the proposed treatment; (2) description of the means of administration; (3)expected side effects or risks which are a "reasonable possibility", including side effects from medications and psycho-pharmaceutical drugs; (4) explanation of alternative treatment modes and services; (5)details of probable consequences of not receiving the proposed treatment; (6) information that the consent is temporary, effective for a limited period of up to 15 months; and (7) the patient's right to withdraw informed consent at any time in writing. The patient is given a copy of the completed informed consent upon request.

Continued on page 3

Inside This Issue

A new study just showed that exenatide injected in to type 2 diabetics helped achieve positive results on fasting and postprandial glycemia over placebo. Guess what exenatide is? It is an experimental peptide that was originally extracted from Gila monster spit.

New Drugs

Doug Englebert Pharmacy Practice Consultant PRQI

Brand Name	Generic Name	Use
Aloxi	Palonosetron	For acute nausea and vomiting from chemotherapy.
Boniva	Ibandronate	For treatment of postmenopausal osteoporosis.
Crestor	Rosuvastatin	For lowering cholesterol.
Cubicin	Daptomycin	For complicated skin infections.

Medication Errors

Doug Englebert Pharmacy Practice Consultant

What's in a name? Take a look at the brand names of the medications in the list above. Do you wonder who comes up with these names? In reality, drug names go through various evaluations in order to avoid having names that are similar, i.e. the sound-a-like or look-a-like phenomena. For example, the proposed drug name goes through handwriting tests to see if the handwritten name looks like other medication names that are already out on the market.

Unfortunately sound-a-like and look-a-like medication names still make it through the process. Therefore, it is important for telephone and verbal orders to be avoided and only used in rare instances. If verbal or telephone orders are used, special precaution should be taken by the receiver of the order to repeat and spell out what was heard.

Tehy say taht as lnog as you hvae the frist and lsat letetrs of a wrod corerct your mnid flils in the rset.

The sentence above makes a strong case for advocating that verbal, telephone and illegible orders be avoided. If they are used promote repeating orders and spelling back what was heard or what was seen.

Focus Drug of the Month

Doug Englebert
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Generic or Brand?

Instead of focusing on a specific medication this issue we will look at brand and generic drug issues.

First lets talk about some basic perceptions about the word "generic". Some of us remember when generic foods were on the store shelves. They usually came in white packages with black lettering and the general consumer response was that the product was not as good as "name brands" that were available. Therefore consumers bought name brands instead of the generic products. That is probably why we do not see "generics" on our store shelves packaged that way anymore.

In the case of medications, when the FDA approves a new drug, the company that discovered the medication has patent exclusivity for a specified period. That means that no other company can make that medication during that time period. This original medication is termed the brand medication. Once the patent time limit is reached, other companies can make that medication. These other company's products are called generics.

The FDA process rates generics, those that are "A" rated are considered brand equivalent. In reality "A" rated generic medications and brand medications are virtually one and the same. They may be different colors and different shapes but the active ingredient is identical.

If there are medications you would like featured in this column, please send an email to Doug at engleda@dhfs.state.wi.us

Continued from page 1- Informed Consent

The informed consent document is not valid unless a competent patient has signed it or, if the patient is incompetent, his guardian has signed it. Competence means "substantially able to understand" all significant information which has been explained in easily understandable language, or the consent form has been signed by the legal guardian of an incompetent patient or minor. Except in emergencies, no treatment nor medication may be given without the prior informed consent of the patient, unless the patient has been found not competent to refuse medication and treatment under s. 51.61 (1) (g), Stats., and the court orders medication or treatment. For a patient found incompetent under ch. 880, Stats., the informed consent of the guardian is required. In the case of a minor, the informed consent of the parent or guardian is required. Informed consent for treatment from a patient's parent or guardian may be temporarily obtained by telephone.

In the event that a signature is not obtainable, the program shall prepare the informed consent for the treatment record and indicates the activities carried out to obtain a signature. The person seeking the informed consent signs this document. Under emergency situations some exceptions to prior written consent to treatment are permissible. In those events, informed consent shall be obtained as soon as practicable. Oral consents or the risk of immediate harm shall be documented in the patient's record, along with details of the information verbally explained to the parent or guardian about the proposed treatment. Verbal consent is valid only for a period of 10 days. There are no exceptions for research or drastic treatment procedures.

A voluntary patient may refuse any treatment, including medications, at any time and for any reason, except in an emergency, though it may result in treatment referral or discharge. Any patient who does not agree with all or any part of his or her treatment plan shall be permitted a second consultation for review of the treatment plan.

Patient treatment records shall include: (a) a specific statement of the diagnosis and an explicit description of the behaviors and other signs or symptoms exhibited by the patient; (b) documentation of the emergency when emergency treatment is provided to the patient; (c) clear documentation of the reasons and justifications for the initial use of medications and for any changes in the prescribed medication regimen; and (d) documentation that is specific and objective and that adequately explains the reasons for any conclusions or decisions made regarding the patient.

A physician ordering or changing a patient's medication must ensure that other members of the patient's treatment staff are informed with the expected benefits and potential side effects, which may affect the patient's treatment. The physician is required to routinely review the patient's prescription medication and document that review. Each inpatient and residential treatment facility that administers medications must have a peer review committee or other medical oversight mechanism reporting to the facility's governing body to ensure proper utilization of medications. A properly completed informed consent integrated into the patient's treatment plan and record brings a standard of care that values the patient for their inherent worth and trusts that patients should be involved and, in part, responsible for their own care.

Grievance Procedures

If a patient or legal representative believes his/her rights, including the informed consent rights, have been violated, has reason to complain about the treatment s/he received, or the manner in which s/he was treated, s/he can file a complaint or grievance to seek resolution of the issue. Every facility and program is required to have a written grievance complaint process with appeal rights. HFS 94 grievance procedures provide for both informal or formal grievance resolution. The first step in seeking resolution of a complaint is to ask the facility for the client rights specialist (CRS) or how to file a complaint. The CRS should be knowledgeable in managing the entire complaint process from beginning to resolution.

NOTE: HFS 94 prohibits retaliation against a complainant and protects the complainant's right to seek a judicial review of the complaint.

The specific requirements in HFS 94 and Chapter 51, Wisconsin Statutes, may not apply to all situations regarding informed consent. However, in most cases individuals who receive care in regulated facilities in Wisconsin must be informed about the care they receive. Facilities should, at a minimum, follow the regulations that specifically apply to their circumstance.

Continued page 4

Consultant's Corner

Doug Englebert *Pharmacy Practice Consultant PRQI*

This section will appear in each issue and will contain information that will answer your questions. If there is a topic about which you want more detailed information, please drop me an email at engleda@dhfs.state.wi.us and I'll research the topic.

1. ***Does the facility need to do an ECG prior to starting Geodon?***
   Geodon is an antipsychotic approved for treating schizophrenia. The Food and Drug Administration (FDA) approved this medication with the package labeling or package insert that indicates there is a risk of arrhythmia with this medication. The labeling suggests that ECG may be beneficial for individuals who are at risk. From a surveyor perspective, most regulations do not require that an ECG be performed. However, nursing home regulations do require that medications are monitored and the benefits of the medication should outweigh the risks. One component for measuring risk may be an ECG. Surveyors may look for the ECG monitoring but would look for other signs of monitoring. Facilities may have justifiable reasons for not doing ECGs.

2. ***Do medications need to be destroyed upon discharge?***
   Many facility regulations have requirements regarding medication destruction. For Example, in hospitals, since the medication system is a closed system, medications are usually only destroyed when the medication expires. In community settings, like nursing homes, some medications may be able to be returned to the pharmacy. Those medications that can not be returned may need to be destroyed. In contrast, in assisted living facilities none of the medications can be returned to a pharmacy. Currently HFS 83 requires a Community Based Residential Facility (CBRF) to destroy the medications, in a timely manner, upon discharge for any reason. However, a facility must balance the medication destruction requirements against the discharge requirements. For example, many of the discharge regulations require a facility to assure the residents or patients needs are going to be met upon discharge. This means that in many situations the facility needs to provide medications. In addition, in community settings like nursing homes and CBRFs the medications are the resident's property. In these situations, if the medication the resident is taking is being continued, those medications can be given to the resident to continue taking at their next location. Facilities, therefore, need to balance the requirements for medication destruction against other requirements that apply, like discharge and resident or patient property rights.

3. ***What should a nursing home do about administering medications to residents who are newly admitted and there is no medication administration record (MAR) available?***
   First and foremost, residents who are newly admitted should have their needs immediately assessed and met. Therefore, if a medication is needed and the facility decides they can not give the medication because they have no MAR available, then most likely a resident's need is not being met and a violation of regulations has occurred. It is important for facilities to document that medications were given, as that documentation acts as the communication record between healthcare professionals. Without accurate complete communication the possibility exists that medications could be given too many times or not at all.

   In some facilities, when a new resident is admitted, the pharmacy provider generates the MAR. In these situations receipt of the MAR may take a couple hours. In the interim facilities may wish to adopt alternative methods for documenting medication administration. Some wish to avoid multiple transcriptions and may chose to photocopy physician's orders and use that photocopy sheet to document medication administration. There are many other processes facilities may adopt. The critical issue is that persons responsible for medication administration know what has or has not been done for new admissions. That communication should be in one location, be accurate, and must be complete.

Continued from page 3

The client rights and grievance brochure may also be obtained by going to the DHFS web site links below:
http://dhfs.wisconsin.gov/bqaconsumer/publications/ClientsRtsEngRed.pdf

References are available upon request.